HOUSE
STUDY
GROUP bill analysis

HB 10
Leland
CSHB 10
Von Dohlen

SUBJECT: Generic substitution of drugs

COMMITTEE: Health and Welfare recommends it do pass, as substituted

VOTE: 7 ayes--Madla*, Whitehead, Delco, Glossbrenner*, Gonzales*, Miller*, Von Dohlen

4 nays--Ezzell, Orr, Untermeyer, Vaughn

1 present, not voting--J. Wilson

1 absent--Florence

WITNESSES: For--Richard O. Yates, secretary, Texas Joint Legislative Committee of the National Retired Teachers Association and the American Association of Retired Persons; Dr. James T. Dolusio, dean of pharmacy, UT College of Pharmacy; T. L. Vordenbaumen, Texas Pharmaceutical Association; etc.

Against--Ace Pickens, Texas Medical Association; Waymon Drummond, doctor of internal medicine, C. V. Roman Medical Society and National Medical Association; Dordie Johnson, consultant, National Alliance of Senior Citizens; Carl R. Smith, Dallas County Pharmaceutical Society; William R. Lloyd, research pharmacist, Texas Pharmaceutical Co.; John H. Boyd, Texas Oesteopathic Medical Association; etc.

DIGEST: This bill allows pharmacists to substitute, within limits, certain generic drugs.

The bill creates a new State Formulary Commission within the State Board of Pharmacy. The board will consist of three pharmacists and three physicians and will set the guidelines for generic substitution.

The board will maintain and publish two lists--one of approved manufacturers and another of drugs which may not be substituted (a so-called "negative formulary"). The bill already contains the names of more than 100 drugs to be included on the initial negative formulary. (These drugs come from a list prepared by the federal Food and Drug Administration.)

The board has power to amend this list and shall revise the formulary at least once every six months and distribute it to licensed pharmacists in the state.

Pharmacists are authorized to substitute any drugs produced by an approved company, but not on the negative formulary. The pharmacists must tell patients of the substitution, and patients may order no substitution. Doctors may also block substitution by writing "dispense as written" on the prescription.

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PRO: The case for generic substitution of drugs is well-established by now. Doctors often prescribe medication by brand name. These drugs are familiar to doctors because major drug companies have spent millions of dollars promoting them. Pharmacists often have identical drugs on their shelves at a fraction of the cost. But state law now prohibits substitution.

Asprin, to cite the simplest example, is available under expensive brand names promoted on television. It is also available at only a few cents on the dollar under nonadvertised house brands. The same principle holds for hundreds of antibiotics and other complex drugs. The only difference is that the patient is now unable to choose freely among the less expensive alternatives.

Why should the poor and the elderly, especially, be forced to pay premium prices for brand names when the same drugs (often from the same companies) are available for less money as generics? Many hospitals, nursing homes and other health care facilities already buy drugs this way. And about 20 other states have already opened the door to some form of generic substitution.

Many of the complaints against previous generic substitution bills have been answered by this bill:

1. A board of medical and pharmaceutical experts will set guidelines to prevent willy-nilly substitution of nonequivalent or substandard drugs.

2. Disreputable manufacturers will not be listed, and their drugs may not be substituted.

3. Unique drugs--those for which there are no "bioequivalent" drugs--will be listed on the negative formulary and may not be substituted.

4. A doctor may prevent substitution with the stroke of a pen.

5. And the patient may also order no substitution.

HB 10, in short, represents a major compromise between the advocates of open, unrestricted substitution and those who fear that any substitution will mean lower quality. This bill offers restricted substitution. Notice the mix of liberals and conservatives who voted for it in committee.

It's natural for the profit-making drug firms to try to defend their market shares by arguing against generic substitution. They try to convince folks that a drug from Company A is, somehow, better than an identical, less expensive drug from Company B. But these arguments for restricted competition must be weighed against the economic self-interest of the companies.

Some critics say generic substitution will increase malpractice suits against pharmacists. But recent evidence from Michigan, where there is not even a formulary board to oversee the substitution process, shows no effects on malpractice. And less than 1 per cent of the prescriptions in that state are marked "dispense as written"--evidence that doctors there have accepted generic substitution.

CON: Generic substitution is politically attractive, but medically dangerous. And the alleged cost-savings of substitution have not been proven conclusively in any of the states that have tried it.

There are important differences in quality among manufacturers--even manufacturers that meet FDA stands (which, by the way, are looser and less well-enforced than many care to admit). We all recognize differences among products as mundane as colas or soaps. Is it unreasonable to expect the same differences among drug manufacturers? Many companies have earned the confidence of the medical community, and that confidence should be respected.

Generic substitution sounds simple, but isn't. It sounds reasonable to say that two "chemically equivalent" drugs can be substituted. But chemical equivalency refers to active ingredients. Drugs usually contain other ingredients and are compounded differently. There are 32 recognized ways drugs can differ. As a result, supposedly identical drugs often behave differently. One may get into the bloodstream quicker or last longer. The key comparison, rather than chemical equivalence, must be "bioequivalence"--the comparison between the effects of two drugs on the human body. Even HB 10 recognizes this comparison in principle. But the complicating factor is that bioequivalence is <u>unproven</u> for must drugs. Even the formulary board cannot expect to contract for enough research to settle all the existing issues. This bill presumes the corner druggist will be able to settle these fine points of bioequivalence when, in fact, the research on many drugs is incomplete or ambiguous. The "negative formulary" will prohibit many dangerous substitutions, but will do nothing to guide pharmacists on the close calls.

Doctors should decide which drugs to prescribe (or whether to prescribe a generic). His decision is based on the actual medical history of the patient, including any reactions to particular drugs, and on clinical experience with certain brand names and families of drugs. The medical literature already includes several horror stories of patients whose prescriptions were substituted without the physician's knowledge, often causing unintended side effects or resulting in dangerous combinations of medication. This bill drives a wedge between the patient and doctor. The "dispense as written" rule is little protection because it puts an onerous chore on the doctors; they don't have time to write it dozens of times a day.

And what about liability for malpractice when a substitution backfires? Is the doctor liable for his failure to block the substitution? Or is the pharmacist responsible? Or the state, which allowed the substitution by failing to put it on the negative formulary? Or, is no one responsible?

Generic substitution also saves little or no money for patients. Sure, there are some spectacular individual cases. But where is the evidence that consumers, as a class, receive significantly lower prices in states that allow substitution? There isn't any such evidence. In fact, some evidence suggests that prices go up.

In sum, generic substitution offers questionable gains, but very real and dangerous risks.

COMMENTARY: Rep. Leland plans a floor amendment to say that pharmacists have the same malpractice liability under this bill as they do under existing law when they fill a prescription that allows generic substitution.

The pharmacy profession originally backed many of the anti-substitution laws to fight drug counterfeiting and unethical substitution of cheap, shoddy drugs for good ones.

The present generation of druggists, however, has generally shifted to supporting substitution as a cost-saving measure and--it seems--as a new assertion of professional competence to handle such matters, rather than to serve simply as technicians in the shadows of doctors.

The major drug companies, naturally, have opposed the new trend and have been supported strongly by doctors, who feel their professional responsibilities are being eroded. A counter-movement within the pharmacy profession questions whether generic substitution is supported by scientific evidence.

The Hobby-Clayton Commission urged the Legislature to enact a generic substitution bill very similar to CSHB 10. It "should permit consumers to take advantage of considerable cost savings," the commission said, citing a $400,000 annual savings in the Texas Vendor Drug Program under a limited federal program. The Texas Pharmaceutical Association estimates Texas consumers would save $12-$75 million a year. Critics question that estimate.

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